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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,193	03/24/2005	Anu-Maria Loukola	PB0262	6686

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EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**PAPER NUMBER**
1634	

MAIL DATE	DELIVERY MODE
07/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,193	LOUKOLA ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-64 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-64 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, 12-14, 22-32, 51-54, and 56, drawn to polynucleotides.

Group II, claim(s) 10, drawn to polypeptides.

Group III, claim(s) 11, drawn to antibodies.

Group IV, claim(s) 15-20 and 46-50, drawn to diagnostic methods comprising detection of one or more SNPs in nucleic acids.

Group V, claim(s) 21, drawn to diagnostic methods employing antibodies.

Group VI, claim(s) 33-45, drawn to treatment methods comprising SNP detection.

Group VII, claim(s) 55, drawn to methods of metabolizing a chemical employing a host cell.

Group VIII, claim(s) 57-59, drawn to haplotypes.

Group IX, claim(s) 60, drawn to diagnostic methods comprising haplotype analysis.

Group X, claim(s) 61, drawn to diagnostic methods employing antibodies in haplotype analysis.

Group XI, claim(s) 62-64, drawn to treatment methods employing haplotype analysis.

2. The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. Inventions I-XI share

a technical feature in that each of the Inventions is drawn to, or involves the use of polynucleotides encompassed by Invention I, or the use of polypeptides encoded thereby, antibodies specific for said polypeptides, or information (e.g., haplotypes) derived from said polypeptides. However, it is noted that Invention I encompasses, e.g., pentamers and other short fragments of SEQ ID NOS recited in the claims of Invention I, such that the prior art clearly anticipates molecules encompassed by the claims. Thus, the technical feature shared by Inventions I-XI cannot constitute a special technical feature as set forth in PCT Rule 13.2. Further, Inventions I-XI do not share any other technical feature that might constitute a special technical feature within the meaning of PCT Rule 13.2. Therefore Inventions I-XI lack unity of invention with one another.

Further restriction requirement applicable to all Groups

3. Groups I-XI each encompass a multitude of distinct biomolecules or fragments thereof, and/or combinations thereof, and/or information derived therefrom (e.g., haplotypes), which distinct biomolecules also lack unity of invention with one another.

In particular, Group I encompasses a variety of polymorphic sequences and SNPs as set forth in claims 1, 6-7, 22-23, 25, 27-28, and 51. Group II encompasses a variety of different polypeptides, while Group III encompasses a variety of different antibodies (see text of claims 10-11, noting dependency on claim 1). Group IV encompasses a variety of different SNPS (see claims 15, 17 and 46-47), and well as a variety of corresponding oligonucleotides (claim 20). Group V encompasses the use of a variety of different polypeptides (claim 21). Group VI encompasses the use of both a

variety of different SNPs (claims 33, 35-36, 39-40, 42-43) and different antibodies (claim 45). Group VII encompasses the use of a variety of different cells (claim 55). Group VIII encompasses a variety of different information combinations (haplotypes)(claims 57-59), while Groups IX and XI encompasses the use thereof in diagnosis (Group IX, claim 60) and treatment (Group XI, claims 62—64), respectively. Group X encompasses the use of polypeptides encoding by one of the different haplotypes (claim 61). Each biomolecule and/or combination encompassed by the Groups as noted above has a unique combination of structural features and functional properties, such that the various combinations cannot be regarded as being "of a similar nature," and thus lack a special technical feature under PCT Rule 13.2 (see Annex B of the Administrative Instructions under the PCT).

Accordingly, if any of Groups I-XI, Applicant must further elect a single biomolecule or combination thereof from those encompassed by the claims as specified above for examination. **This is not an election of species. Applicant is advised that examination of the claims will be restricted to the elected biomolecule or combination.** It is also noted that for those Groups encompassing, e.g., the use of more than one type of biomolecule within a method (e.g., a nucleic acid and an antibody), Applicant may choose to elect multiple molecules corresponding to one another and usable together in the method of the invention.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571/272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Diana B. Johannsen
Primary Examiner
Art Unit 1634